

Office Action Summary	Application No.	Applicant(s)	
	10/788,414	MIRKIN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-40 and 42-129 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>3/20/09</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/08</u> . | 6) <input type="checkbox"/> Other: _____. |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,8-13,15,16,18,20,22,28-33,42,43,45,47-51,53,54,56,58,60,66-70,73-79 and 86.

Continuation of Disposition of Claims: Claims rejected are 1,7,14,17,19,21,23-27,34-40,44,46,52,55,57,59,61-65,71,72,80-85,87-92,94-99,110-115 and 117-129.

DETAILED ACTION

Response to Amendment

1. Claims 1, 3, 4, 6-40 and 42-129 are currently pending.
2. Claims 3, 4, 6, 8-13, 15, 16, 18, 20, 22, 28-33, 42, 43, 45, 47-51, 53, 54, 56, 58, 60, 66-70, 73-79 and 86 are currently withdrawn.
3. Claims 1, 7, 14, 17, 19, 21, 23-27, 34-40, 44, 46, 52, 55, 57, 59, 61-65, 71, 72, 80-85, 87-92, 94-99, 110-115 and 117-129 are currently under examination.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(3) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/382,596 and 60/418,179, fail to provide adequate support or enablement in the manner provided by the first paragraph of

Art Unit: 1641

35 U.S.C. 112 for one or more claims of this application. The provisional applications do not provide support for the limitation of modifying a tip with a selected hydrophilic compound.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low" in claims 7, 46, is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, it is unclear the range of molecular weights that polyalkylene glycol compounds could have to qualify as being "low," rendering the claim ambiguous and indefinite.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 7, 14, 17, 19, 21, 23-27, 34-40, 44, 46, 52, 55, 57, 59, 61-65, 71, 72, 80-85, 87-92, 94-99, 110-115 and 117-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to

Art Unit: 1641

comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, with respect to claims 1, 40, 90, 91, 110-112, 120, , applicant fails to provide sufficient support for all hydrophilic compounds. As applicant has noted in the arguments filed August 19, 2009 (see p.15) and also in the specification (see example 2), not all hydrophilic compounds are capable of inhibiting protein adsorption. Furthermore, applicants have only provided one representative example of a hydrophilic compound capable of inhibiting protein adsorption, specifically, Si-PEG, which would not be representative of all hydrophilic compounds. Furthermore, applicants have not provided guidance on the physical and/or chemical properties of the compounds that would resist protein adsorption, other than that they are hydrophilic, which would not lead to inhibition of protein adsorption.

9. Claims 1, 7, 14, 17, 19, 21, 23-27, 34-40, 44, 46, 52, 55, 57, 59, 61-65, 71, 72, 80-85, 87-92, 94-99, 110-115 and 117-129 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydrophilic compounds comprising Si-PEG to inhibit protein adsorption, does not reasonably provide enablement for all hydrophilic compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. In particular, based on the specification and applicant's own arguments, not all hydrophilic compounds would inhibit protein adsorption, and in fact, many hydrophilic compounds would

Art Unit: 1641

actually facilitate protein adsorption (see example 2). Therefore the limitation of "a tip modified by a layer comprising a selected hydrophilic compound" in order to "inhibit protein adsorption" would only be enabled with respect to a limited number of hydrophilic compounds. Of these hydrophilic compounds³, applicants have only provided guidance on one specific hydrophilic compound that would be capable of inhibiting protein adsorption, specifically Si-PEG.

Furthermore, applicants have not provided guidance on the physical and/or chemical properties of the compounds that would resist protein adsorption, other than that they are hydrophilic, which would not lead to inhibition of protein adsorption. Since there a large variety of hydrophilic compounds, of varying levels, there would be required a large amount of experimentation to determine which hydrophilic compounds would in fact resist protein adsorption.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/

Primary Examiner, Art Unit 1641